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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/529,008	01/03/2006	Sanjay Suri	05-40052-US	8800

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EXAMINER	
DESAI, RITA J	

ART UNIT	PAPER NUMBER
1625	

MAIL DATE	DELIVERY MODE
08/05/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/529,008	SURI ET AL.	
	Examiner	Art Unit	
	Rita J. Desai	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 April 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-20 are pending.

Claims 16-20 are new.

Response to the arguments:-

The rejection under 35 USC 103 as being unpatentable over WO -A-95 10514 ("WO 95"), Iwasaki et al., 1999, Chemical And Pharmaceutical Bulletin, JP (11-1999), Vol.42, pages 2285-2290 ("Iwasaki") Sejas et al., 1998, Tetrahedron, 44:6197-6200 ("Sejas") WO-A-9631478 ("WO 96"), EP 0,208,855 ("EP '855"), EP 0,152,897 ("EP '897"), US 4,659,716 ("'716 patent"), or HU 194,864 ("HU '864") independently and also all in view of Peon et al., 2002, J. Am. Chem. Soc. 124:6428-6438 ("Peon")). Still stands .

The arguments are not found to be persuasive.

Applicants are arguing the Peon Jorge et al reference. It should be noted that the examiner has made the rejections independently.

The Peon reference is used just to validate the point even further.

With regard to the '716 patent, it suggest the use of KOH and EtOH/Water (1:1) for 66 hrs or NaOH and 70% EtOH for 24 hrs with yield ranging from 90 to 95%. It does not teach or suggest the claimed process for the production of desloratadine by reacting loratadine with neat alcohol in the presence of inorganic base and isolating desloratadine in crystalline form by the addition water to the reaction mixture. With regard to the "neat alcohol" limitation, the Examiner appears to admit that '716 patent does not teach or suggest that limitation when the reference is considered independently. However, the Examiner appears to contend that the '716 patent in combination with the Peon reference (see the Office Action at 5, where it is stated that "[t]he Jorge reference just explains the mechanism with the neat alcohol") suggests the claimed process.

The arguments are incorrect. The examiner stated Us 4659716 in column 4 , lines 38-39 teaches using a neat t-butyl alcohol, in the process of preparing Loratadine.

The rejection over US '716 has been withdrawn as applicants have amended the claims to specify reacting the starting compound.

The arguments with regards to the " US 55959971 (the '997 patent), it teaches saponification of loratadine at column 11, lines 6-14 as follows: Loratadine (4.0 g) was added to a solution of sodium hydroxide (5.9 g) in 280 mL of absolute ethanol and the mixture was stirred at reflux for four days. The mixture was cooled and concentrated to remove ethanol. The residue was diluted with water and aqueous layer was extracted with methylene chloride five times. The combined organic layer was washed with water, brine and dried over sodium sulfate. The solvent was evaporated to give 2.82 g (87%) of pure loratadine derivative (or metabolite) as a pale-tan solid.

It does not teach or suggest the claimed process for the production of desloratadine by reacting loratadine with neat alcohol in presence of inorganic base and isolating desloratadine in crystalline form by the addition water to the reaction mixture. If anything, it teaches away not toward, the claimed process. It teaches a process requiring, among other things, removal of ethanol and extractions with methylene chloride. Further, it teaches a process requiring at least four days. Furthermore, the product obtained is "pale-tan solid." In contrast, Applicant is claiming an improved process without requiring removal of ethanol or extractions with methylene chloride and the claimed process can be completed in a significantly shorter time period (see, for example, Example 1) than that suggested by the '997 patent, and the product obtained is not colored. Peon, discussed above, does not and cannot remedy the deficiencies "

It should be noted that applicants claim reads

1. (Currently Amended) An improved process for the production of Desloratadine which comprises, reacting starting compound loratadine with neat alcohol in presence of inorganic base, and isolating the title compound in crystalline form by conventional methods on addition of excess water.

It is " comprising " the steps and hence open language and could include the process of removing the alcohol and extracting it with other solvents.

The claims further is not limited to the type of product obtained and what period of time. Limitation in the specifications cannot be read into the claims.

Thus the rejection on '997 patent still stands.

Regarding crystallization t, the examiner has provided a very good reference by Ludwig Gutterman which clearly teaches crystallization as a process of purification.

The examiner is repeating it here.

subjected to a process of purification before they can be further utilised. For this purpose the operations most frequently employed are:

1. Crystallisation.
2. Sublimation.
3. Distillation.

CRYSTALLISATION

Methods of Crystallisation. — The crude product obtained directly as the result of a reaction is, in case it is a solid, generally amorphous or not well crystallised. In order to obtain the compound in uniform, well-defined crystals, as well as to separate it from impurities like filter-fibres, inorganic substances, by-products, etc., it is dissolved, usually with the aid of heat, in a proper solvent, filtered from the impurities remaining undissolved, and allowed to cool gradually. The dissolved compound then separates out in a crystallised form, while the dissolved impurities are retained by the mother-liquor. (*Crystallisation by Cooling.*)

The reference articulates it well enough.

Applicants recite the claims as a Jebson format , however the improvement has not been described clearly in the specifications nor the claim. The specification states that the samples do develop a color. See page 7.

Also applicants compounds use various solvents without specifying that it is a "neat" .

The examples indicate that the reaction time is very different in each case, hence the argument that applicants reaction is an improvement because it is faster is also incorrect. Example 6 was completed in 50 hrs. Example 2 was carried out in 12 hours.

Thus the rejection still stands.

Conclusion

Claims 1-20 stand rejected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rita J. Desai whose telephone number is 571-272-0684. The examiner can normally be reached on Monday - Friday, flex time..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Rita J. Desai/
Primary Examiner, Art Unit 1625

R.D.
July 21, 2008